K051965

510 K Summary

JUN 16 2006

Submitted by: Merete Medical GmbH
Alt Lankwitz 102,
12247 Berlin, Germany

US Contact Person: Carl Knobloch
5349 Red Leaf Court
Oviedo, FL 32765

Device Name: OsteoBridge® IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System

Device Classification: 21 CFR 888.3020 Intramedullary fixation rod

Product Code: HSB

Proposed Regulatory Class: Class II

Predicate Device:

- ACE Aim Humeral Nail (K934643)
- Ace Aim Tibial Nail (K934643)
- Zindrick IM Rod (K882443); Later named ACE AIM Femoral Nail (K871539)
- Synthes Unreamed Humeral Nail (UHM) (K933518)
- Synthes Unreamed Tibial Nail (UTN) (K914453)
- Russell-Taylor Femoral Nail (K893377)
- Metagen Segmental Defect Replacement System (K980609)
- Howmedica Modular Proximal Humerus Replacement System (K954559)
- Zimmer Femorotibial Medullary Nail (K853250)

Clinically Related Devices:

- Modular Oncology System Technology (K960626)
- SOS Proximal Femur (K933281)
- Modular Intercalary Humeral Spacer (Mayo Clinic) (Damron *et al*, 1996)

Device Description:
OsteoBridge® IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System is a series of modular intramedullary rods segments that may be used as either proximal or distal segments. The segments are designed to be attached together to form a complete intramedullary rod using semicircular hollow attachment shells that are clamped together with multiple screws to create a complete intramedullary rod and bridge the bone loss/resection of the middle section of either humerus, tibia or femur. Reducing bushings allow the use of different diameter nails proximally and distally to provide optimal fit of the intramedullary nail with the medullary canal of the proximal and distal segments of the bone to be fixed. All components of the OsteoBridge® Humeral IDSF - Intramedullary Segment Fixation Rod System are manufactured from Ti-6Al-4V Titanium Alloy conforming to ASTM F-136. The device is divided into three categories/product size ranges that are suitable for each boney application; humerus, tibia or femur (see tables below).

Humerus			
Attachment Shell		**Nail**	
Dia [mm]	Length [mm]	Dia [mm]	Length [mm]

20	40, 50, 60, 70	7	60, 70, 90
		8	60, 70, 90
		9	60, 70, 90
		10	60, 70, 90, 110, 130

The Nails diameter 7 mm and 8 mm accept interlocking bone screws in diameter 3,8 mm.
The Nails diameter 9 mm and 10 mm accept interlocking bone screws in diameter 5,0 mm.

Tibia			
Attachment Shell		**Nail**	
Dia [mm]	Length [mm]	Dia [mm]	Length [mm]
25	40, 50, 60, 70	9	60, 70, 90
		10	60, 70, 90, 110, 130
		12	70, 90, 110, 130, 150
		14	90, 110, 130, 150, 200

The Nails diameter 9 mm and 14 mm accept interlocking bone screws in diameter 5,0 mm.

Femur			
Attachment Shell		**Nail**	
Dia [mm]	Length [mm]	Dia [mm]	Length [mm]
30	40, 50, 60, 70	10	60, 70, 90, 110, 130
		12	70, 90, 110, 130, 150
		14	90, 110, 130, 150, 200
		16	110, 130, 150, 200

The Nails diameter 10 mm and 16 mm accept interlocking bone screws in diameter 5,0 mm.

Intended use:
The device is intended to be used in the management of segmental diaphyseal bone loss of either humerus or tibia or femur in oncology patients secondary to radical bone loss and/or resection due to tumors. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Mechanical Testing:
In order to demonstrate that the OsteoBridge® IDSF has the mechanical properties necessary to perform its intended use Merete has conducted mechanical and functional testing according to ASTM F-1264-03. This includes:

- Static Four-Point Bend Test
- Static Torsion Test
- Four-Point Bending Fatigue Test
- Three-Point Bending Fatigue Test of the IDSF Locking Screws

The "worst case" of each category (humeral, tibial, and femoral) was tested.

4. Standards

- OsteoBridge® IDSF is produced from titanium alloy Ti-6Al-4V according to ASTM F-136 and ISO 5832/3.
- Mechanical tests have been carried out according to ASTM F-1264-03.
- The sterile components are sterilized according to ANSI/AAMI ST32-1991; Method I
- We recommend sterilizing the non sterile components according to the sterility validation Method ANSI ST46-1993-Prevacuum Steam Sterilization of Medical Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2006

Merete Medical GmbH
% Turnkey Integration USA
Mr. Carl Knobloch
5349 Red Leaf Court
Ovieda, Florida 32765

Re: K051965
Trade/Device Name: OsteoBridge® IDSF-Intramedullary Diaphyseal Segmental Defect Fixation Rod System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 1, 2006
Received: June 2, 2006

Dear Mr. Knobloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use of OsteoBridge® IDSF

Indications for Use

510(k) Number (if known): K051965

Device Name: OsteoBridge® IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System

Indications for Use:
The device is intended to be used in the management of segmental diaphyseal bone loss of either humerus or tibia or femur in oncology patients secondary to radical bone loss and/or resection due to tumors. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K051965